Fact Sheet for Patients: Understanding Results from the Zika Virus RNA Qualitative Real-Time RT-PCR Test

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Dear Patient:

If you are pregnant, please ask your doctor for the Fact Sheet for Pregnant Women: Understanding Results from the Zika Virus RNA Qualitative Real-time RT-PCR Test.

You are being given this Fact Sheet because your blood (serum) was tested for evidence of Zika virus infection. This testing is being done because you have symptoms of Zika virus infection and you live in or have traveled to an area with ongoing Zika virus transmission. The test being used on your specimen is called Zika Virus RNA Qualitative Real-Time RT-PCR, which is a laboratory test, designed to help detect Zika virus infections in humans.

This Fact Sheet contains information to help you understand the risks and benefits of using the Zika Virus RNA Qualitative Real-Time RT-PCR test for Zika virus testing. If possible, you may want to discuss with your health care provider the benefits and risks described in this Fact Sheet and any additional questions you may have.

What is Zika virus infection?
Zika virus infection is caused by the Zika virus and is most often transmitted to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her unborn baby. Zika virus can also be sexually transmitted by a man to his sexual partners. Since 2015, a large number of Zika virus cases have been reported in many South and Central American countries.

Most people who are infected with Zika virus do not have any symptoms. Those that do usually have mild illness with symptoms that may include fever, joint pains, rash, or redness of the eyes. These symptoms often resolve on their own within a week.

Although the Centers for Disease Control and Prevention (CDC) is still investigating the potential harms from Zika virus infection, it has concluded that there is enough scientific evidence to state that Zika virus infection during pregnancy is a cause of birth defects (such as microcephaly) and other poor pregnancy outcomes. Zika virus infection in a pregnant woman does not definitely mean she will have pregnancy problems. However, a woman who is infected with Zika virus during pregnancy is at increased risk of miscarriage, having a baby that is stillborn, or having a baby that is small at birth, has incomplete brain development (microcephaly), and/or eye problems. Women who get Zika virus while pregnant should be monitored more closely by their health care providers throughout their pregnancy. There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

What is the Zika Virus RNA Qualitative Real-Time RT-PCR?
The Zika Virus RNA Qualitative Real-Time RT-PCR is a laboratory test designed to detect Zika virus. The Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why was my sample tested using the Zika Virus RNA Qualitative Real-Time RT-PCR?
You were tested because you have symptoms that resemble Zika virus infection and because you live in or have traveled to an area with Zika virus. The sample collected from you was tested using the Zika Virus RNA Qualitative Real-Time RT-PCR to help find out whether you were infected with Zika virus. The test results, along with other information, could help your doctors make decisions about how to take care of you and may help limit the spread of Zika virus in your community.

What are the known and potential risks and benefits of the Zika Virus RNA Qualitative Real-Time RT-PCR?
You may feel discomfort when the sample is taken. There is a very small chance that the test result is incorrect (see below for more information). The results of this test, along with other information, can help your health care provider make decisions about how to take care of you. Also, knowing your test results may help keep you from giving Zika virus to others.

If this test is positive for Zika virus, does it mean that I have a Zika virus infection?
If you have a positive test, it is very likely that you have a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong; this is called a false positive result. If your result from this test is positive, your health care provider or health department will work with you to help you understand the steps you should take to care for yourself.

If you are male and have a positive test result for Zika virus and you have a pregnant partner or a partner might become pregnant, you should either use a condom the right way every time while your partner is pregnant, or not have sex with your partner to lessen the risk that you may pass Zika virus infection.

If you are female and have a positive result for Zika virus and you have a pregnant partner or a partner who might become pregnant, then you should discuss the risks with your healthcare provider. CDC has indicated that it is not known if females can transmit the Zika virus through sexual contact.

If this test is negative for Zika virus, does it mean that I do not have Zika virus infection?
A negative test for Zika Virus RNA Qualitative Real-Time RT-PCR means that virus was not found in your sample. For Zika virus, a negative result for a sample collected less than a week after the start of illness usually means that Zika virus did not cause your recent illness. It is possible for this test to give a negative result that is incorrect (false negative) in some people with a Zika virus infection. Most people with Zika virus infection have virus in their blood for up to a week following the start of illness. A negative result that is incorrect can happen if your body fights a Zika virus infection faster than most other people do. It can also happen if your illness/symptoms started earlier than the date you first noticed them. In these cases, the virus may already be gone from your blood before the sample is taken for testing.

If your result for the Zika Virus RNA Qualitative Real-Time RT-PCR is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care provider or health department to help you understand the next steps you should take.

What is an Emergency Use Authorization (EUA)?
An EUA is a tool that FDA can use to allow the use of certain medical products for certain emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Zika Virus RNA Qualitative Real-Time RT-PCR, under an EUA.

At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus. FDA has authorized the emergency use of the Zika Virus RNA Qualitative Real-Time RT-PCR to test for the presence of Zika virus in blood. Use of this test is authorized only for the duration of the threat of the emergency, unless it is terminated or revoked by FDA sooner.

How can I learn more?
Information about Zika virus is available at the CDC website: http://www.cdc.gov/zika/index.html. Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Zika Virus RNA Qualitative Real-Time RT-PCR will be made available at the Quest Diagnostics website: http://www.questdiagnostics.com/Zika.

Please also contact your health care provider if you have any questions.